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| APPLICATION NO.                 | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------|-------------|----------------------|---------------------|------------------|
| 10/670,999                      | 09/25/2003  | Andreas Meiser       | WWELL82.001AUS      | 4527             |
| 20995                           | 7590        | 02/08/2008           | EXAMINER            |                  |
| KNOBBE MARTENS OLSON & BEAR LLP |             |                      | WIEST, PHILIP R     |                  |
| 2040 MAIN STREET                |             |                      | ART UNIT            | PAPER NUMBER     |
| FOURTEENTH FLOOR                |             |                      | 3761                |                  |
| IRVINE, CA 92614                |             |                      | NOTIFICATION DATE   | DELIVERY MODE    |
|                                 |             |                      | 02/08/2008          | ELECTRONIC       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
eOAPilot@kmob.com

|                              |                 |               |
|------------------------------|-----------------|---------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s)  |
|                              | 10/670,999      | MEISER ET AL. |
|                              | Examiner        | Art Unit      |
|                              | PHILIP Wiest    | 3761          |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 20 November 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-17 and 26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-6, 9, 11, 15, 16 and 26 is/are rejected.
- 7) Claim(s) 7, 8, 10, 12-14 and 17 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 13 February 2004 is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Amendment***

1. In the response filed 11/20/07, applicant amended claim 26. Claims 1-33 are currently pending, and claims 18-25 and 27-33 remain withdrawn from consideration.

### ***Claim Rejections - 35 USC § 102***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 26 is rejected under 35 U.S.C. 102(e) as being anticipated by Hole (US 2004/0081580). Hole et al. disclose a blood treatment device (i.e. "kit") comprising an oxygenator 32, an analysis gas delivery line 7, at least one venous catheter (48 and 56), and at least one arterial catheter (14 and 16). See Figures 1 and 9. The analysis gas delivered through the delivery line is capable of indicating leakage between a systemic circulation and an artificial circulation.

### ***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1-6, 9, 11, 15, 16, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allers et al. (US 6,287,273).

5. With respect to Claims 1-4 and 9, and 11, Allers et al. (hereafter "Allers") discloses a perfusion system comprising a pump, venous catheter, and arterial catheter for establishing an artificial circulation in a target area of a body, said artificial circulation is isolated from the blood in the systemic body (see Abstract). The device further comprises first means for feeding a substance into the perfusion fluid, said substance being monitored by a variety of sensing means and methods (depending on the type of substance used). Additionally, the system comprises an extracorporeal meter capable of continuously controlling the system (Column 6, Lines 27-37). It is the examiner's opinion that this control meter is capable of shutting off the system if the substance is detected in the systemic circulation. The "first and second means" of claim 1 were interpreted to invoke 35 U.S.C. 116, sixth paragraph because the "means for" statement is not modified by sufficient structure, material, or acts for achieving the specified function.

6. Allers, however, does not disclose that the monitored substance is a gas, specifically laughing gas, and that the sensing means are gas sensors. The use of an analysis gas to detect perfusion fluid leakage creates the same expected outcome as iodine, dye, or other fluids. Additionally, because laughing gas is known in the art as being harmless in small quantities, it is a viable alternative to the substances listed by Allers. Therefore, it would have been obvious to one skilled in the art at the time of invention to modify the perfusion device of Allers with the use of an analysis gas to monitor the leakage of perfusion fluid because doing so performs the same function as the substances disclosed by Allers. Furthermore, if a gas is used to monitor the system,

the use of a gas sensor would have been obvious to monitor the system. See MPEP 2144.07.

7. With respect to Claims 6 and 16, the placement of sensors in the artificial circulation allows for decreases in analysis gas to be measured. A decrease in gas concentration means that some of the perfusion fluid is leaking into the body, being replaced by blood that leaks into the artificial perfusion system. This use of sensors therefore provides the same functionality as the placement of sensors in the systemic circulation. Therefore, the placement of gas sensors in the artificial circulation rather than the systemic circulation for the detection of a leak would have been an obvious rearrangement of parts. See MPEP 2144.04

8. With respect to Claim 26, Allers discloses a kit comprising an oxygenator, a venous catheter, and an arterial catheter. As mentioned above, the use of an analysis gas instead of a liquid such as iodine or a radio marked substance would have been an obvious substitution that performs the same function (see above).

9. Claims 5 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allers in view of Burton (WO 01/43804). Allers discloses the invention of Claims 1 and 3, but does not disclose that the substance can be detected in air exhaled from the body. Burton discloses a bio-mask with integral sensors that may be used to measure the presence of gases in a patient's breath. It is well known in the art that an analysis gas (laughing gas, for example) will be exhaled when it is present in the blood stream. Therefore, it would have been obvious to one skilled in the art at the time of invention to

use the mask of Burton to sense the presence of an analysis gas in the body during usage of the device of Allers. Doing so would enable the presence of analysis gas in the blood to be detected so that the system may be shut down, thereby preventing the injection of dangerous chemicals into the patient's body.

***Allowable Subject Matter***

10. Claims 7, 8, 10, 12-14, and 17 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art does not teach or suggest the use of analysis gas sensors placed in an air outlet line of the oxygenator, nor is it disclosed that an additional gas sensor is provided in the analysis gas delivery line. While it would have been obvious to rearrange the sensors such that they are present in the artificial circulation, the precise placement of said sensors in these locations would not have been obvious. The prior art discloses the use of markers such as iodine to identify a perfusion leak. Therefore, it would not have been obvious to supply a sensor at the oxygenator because sensing for iodine (or other indicators) upstream of the perfusion site would serve no benefit.

Applicant specifically discloses the criticality of a sensor located in the oxygenator on pages 10-11 of the specification, as per claims 7 and 17. Additionally, the prior art does not expressly teach or suggest the use of laughing gas as an analysis gas in a perfusion system. The use of laughing gas has the added benefit of being detectable in the patient's blood or exhaled breath.

***Response to Arguments***

11. Applicant's arguments filed 11/20/07 have been fully considered but they are not persuasive.

Applicant has provided no evidence to establish an unobvious difference between the claimed product and the prior art, but rather has merely argued such alleged difference. Mere arguments can not take the place of evidence. *In re Walters*, 168 F.2d 79,80, 77 USPQ 609,610 (CCPA 1948); *In re Cole*, 326 F.2d. 769,773, 140 USPQ 230,233 (CCPA 1964); *In re Schulze*, 346 F.2d 600,602, 145 USPQ 716,718 (CCPA 1965); *In re Lindner*, 457 F.2d 506,508, 173 USPQ 356,358 (CCPA 1972); *In re Pearson*, 494 F.2d 1399,1405, 181 USPQ 641,646 (CCPA 1974); *Meitzner v. Mindick*, 549 F.2d 775,782, 193 USPQ 17,22 (CCPA), cert. Denied, 434 U.S. 854 (1977); *In re DeBlauwe*, 736 F.2d 699,705, 222 USPQ 191,196 (Fed. Cir. 1984).

***Conclusion***

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PHILIP Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/  
Examiner, Art Unit 3761  
2/1/08

TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER

